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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LEFFERS JR, GERALD G	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/513,888	CROCE ET AL.	
	Examiner	Art Unit	
	Gerald G Leffers Jr., PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *06 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,24 and 158-249* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *23 and 24* is/are allowed.

6)☒ Claim(s) *158-249* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application on 12/6/2004 after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/6/2004 has been entered.

In the response filed on 12/6/2004, several claims were cancelled (claims 100-157) and new claims added (claims 158-249). Claims 23-24 & 158-249 are pending and under consideration in the instant application. This action is not final.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 158-235 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **These are new grounds of rejection that are necessitated by applicants' amendment of the claims in the response filed 12/6/2004.**

Newly added claims 158-172 are directed to an isolated polynucleotide comprising a sequence that anneals under "conditions of high stringency" to one of SEQ ID NOS: 1-3, or the complement thereof, and which also necessarily encodes a protein that binds a compound selected from the groups consisting of the amino-terminal 40 KDa fragment of Fez1, tubulin EF1-γ, and an amino-terminal 153-amino acid fragment of EF1-γ.

Newly added claims 173-181 are directed to an isolated polynucleotide comprising a nucleic acid sequence that is "substantially complementary" to SEQ ID NO: 1 and which also necessarily encodes a protein that binds a compound selected from the groups consisting of the amino-terminal 40 KDa fragment of Fez1, tubulin EF1-γ, and an amino-terminal 153-amino acid fragment of EF1-γ. Newly added claims 182-190 are directed to an isolated polynucleotide comprising a nucleic acid sequence that is "substantially complementary" to SEQ ID NO: 2 and which also necessarily encodes a protein that binds a compound selected from the groups consisting of the amino-terminal 40 KDa fragment of Fez1, tubulin EF1-γ, and an amino-terminal 153-amino acid fragment of EF1-γ. Newly added claims 191-199 are directed to an isolated polynucleotide comprising a nucleic acid sequence that is "substantially complementary" to SEQ ID NO: 3 and which also necessarily encodes a protein that binds a compound selected from the groups consisting of the amino-terminal 40 KDa fragment of Fez1, tubulin EF1-γ, and an amino-terminal 153-amino acid fragment of EF1-γ.

Newly added claims 200-211 are directed to an isolated polynucleotide comprising a sequence that anneals under conditions of "high stringency" to a nucleic acid having the sequence of one of SEQ ID NOS: 1-3, or the complement thereof, and wherein the isolated

polynucleotide encodes a protein having an activity selected from the group consisting of inhibiting cellular proliferation and tumor suppression.

Newly added claims 212-223 are directed to a polynucleotide comprising a sequence that is substantially complementary to a nucleic acid having the sequence of one of SEQ ID NOS: 1-3, or the complement thereof, and which encodes a protein that inhibits cellular proliferation. Newly added claims 224-235 are directed to a polynucleotide comprising a sequence that is substantially complementary to a nucleic acid having the sequence of one of SEQ ID NOS: 1-3, or the complement thereof, and which encodes a protein that is a tumor suppressor.

The instant specification teaches that the term "substantially complementary" is meant to convey a limitation of at least a minimum of 70% complementarity between two nucleic acids (e.g. page 24, lines 1-20). The instant specification teaches that the phrase "anneals under conditions of high stringency" is meant to convey a limitation of a minimum of at least 75% complementarity between two nucleic acid sequences (e.g. page 24, line 21 to page 25, line 18). SEQ ID NO: 1 is described in the specification as a portion of the human genome encoding the human FEZ1 protein and comprising over 9 kb of DNA. SEQ ID NO: 2 is described in the specification as a cDNA representing the full-length mRNA for the human FEZ1 protein and is ~5.5 kb in length. SEQ ID NO: 3 is described as a cDNA representing the open reading frame for the human FEZ1 protein and is ~1.8 kb in length (e.g. page 17, legend for Figure 5). SEQ ID NO: 4 represents the full length FEZ1 protein and comprises 596 amino acid residues (e.g. page 18, legend for Figure 5).

As a first matter, there is no direct linkage in the claims between the sequence having the recited complementarity to one of SEQ ID NOS; 1-3, or the complement thereof, and the

encoded protein having the recited binding or functional activity. As currently written, the recited protein could be encoded by any nucleic acid sequence found within the isolated polynucleotide, without any connection to SEQ ID NOS: 1-3. Thus, the claims as currently written encompass an enormous genus of polynucleotide sequences that encode a protein that meets the functional limitations of the claims.

Secondly, even if there were a direct linkage between the sequence having the recited complementarity to one of SEQ ID NOS; 1-3, or the complement thereof, and the encoded protein having the recited binding or functional activity, there is insufficient basis for one of ordinary skill in the art to envision a sufficient number of polynucleotide sequences that have the recited complementarity and which also necessarily encode a protein having the recited activity (i.e. as little as 70% complementarity to one of one of SEQ ID NOS; 1-3, or the complement thereof, and which encodes a protein with the recited binding or functional activities). At most, the instant specification provides significant guidance with regard to SEQ ID NOS: 1-3 that encode the full-length or truncated human FEZ1 protein (e.g. see the working examples). No significant guidance is provided as to what changes can be made over the length of the human FEZ1 protein and still maintain the recited functional or binding activities. Moreover, the prior art does not appear to offset the deficiencies of the instant specification with regard to a structural/functional correlation between nucleic acids having the recited complementarity and which must also possess the recited functional activities. Thus, there is no basis in the originally filed specification and claims for the skilled artisan to envision a sufficient number of specific polynucleotide sequences that meet the structural limitations of the claims and which also meet

the functional limitations of the claims. The skilled artisan would reasonably have concluded applicants were not in possession of the broadly recited polynucleotides on this basis alone.

Further, there is no literal support in the originally filed specification or claims for the broad recitation of a polynucleotide having the recited percentage identity to the recited sequences described by SEQ ID NOS: 1-3 and which encodes a protein having the recited binding or functional activity. The passages pointed to by applicants' response provide, at most, literal support for polynucleotides comprising SEQ ID NOS: 1-3 and which bind the recited polypeptides based upon the working example data for FEZ1 or truncated FEZ1. Nor does there appear to be any sort of inherent support for the broad recitation of a polynucleotide comprising a sequence having the recited complementarity to one of SEQ ID NOS: 1-3 and which encodes a protein having the recited binding activity or function. Therefore, in addition to the specification and prior art not providing a sufficient basis for the skilled artisan to envision a sufficient number of polynucleotides that encode proteins having the recited functional activity, each of the claims is rejected on the grounds of comprising impermissible NEW MATTER.

Claims 236-249 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **These are new grounds of rejection that are necessitated by applicants' amendment of the claims in the response filed 12/6/2004.**

Claims 236-242 are directed to an isolated polynucleotide comprising a nucleotide sequence that encodes a protein comprising SEQ ID NO: 4. Claims 243-249 are directed to an isolated polynucleotide comprising a nucleotide sequence that encodes a protein comprising an amino-terminal 40 KDa fragment of the sequence of SEQ ID NO: 4. SEQ ID NO: 4 represents the full length FEZ1 protein and comprises 596 amino acid residues (e.g. page 18, legend for Figure 5).

There is no literal support in the originally filed specification or claims for claiming literally any nucleic acid sequence that can encode the 596 residue protein represented by SEQ ID NO: 4 or the amino-terminal 40 KDa fragment thereof.

The response filed 12/6/2004 points to pages 17-18 & page 114 for support for claims 236-249. Pages 17-18 provide the legend for Figure 5, which comprises the nucleic acid sequences described by SEQ ID NOS: 1-3 and the amino acid sequence described by SEQ ID NO: 4. SEQ ID NO: 1 is described in the specification as a portion of the human genome encoding the human FEZ1 protein and comprising over 9 kb of DNA. SEQ ID NO: 2 is described in the specification as a cDNA representing the full-length mRNA for the human FEZ1 protein and is ~5.5 kb in length. SEQ ID NO: 3 is described as a cDNA representing the open reading frame for the human FEZ1 protein and is ~1.8 kb in length (e.g. page 17, legend for Figure 5). Nowhere in the cited passages is it evident that applicants contemplated a genus of isolated polynucleotides that encompass literally any nucleic acid that can encode SEQ ID NO: 4. Moreover, it is not clear from the cited passages exactly what amino acid sequence from within SEQ ID NO: 4 is encompassed by the phrase "the amino-terminal 40 KDa fragment of the sequence of SEQ ID NO: 4". For example, the legend for Figure 5 lists several different

truncation sequences for the human FEZ1 protein. Thus, there is no apparent literal or inherent support for the claimed polynucleotides.

Therefore, claims 236-249 comprise impermissible NEW MATTER.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Primary Examiner
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PRIMARY EXAMINER